

**A. IDE No. G940155 - Submissions to FDA
and Responses Through FDA Approval.**

10/28/94 IDE application submitted to FDA by
Gynecare, Inc.

11/02/94 FDA Notice of IDE No. G940155 assigned
for EASY(TM) ENDOMETRIAL ABLATION SYSTEM
(effective November 30, 1994).

09/05/95 Amendment to IDE No. G940155 submitted
for performing efficacy study of the
Gynecare Uterine Balloon Therapy (UBT)
System in comparison with Rollerball
Endometrial Ablation.

09/25/95 Supplemental Application submitted to
IDE No. G940155 updating sections of
revised protocol in response to
September 21, 1995, conference call of
Mr. Pollard of the FDA.

10/02/95 Supplemental application submitted to
update "Other Institutions" section of
IDE No. G940155.

10/05/95 Response of FDA granting conditional
approval of efficacy and safety clinical
study for the UBT.

02/23/96 Response of FDA approving proposed
investigational plan and protocol
changes.

03/31/97 Pre-PMA submission for ThermaChoice™
Uterine Balloon Therapy (UBT) System.

**B. PMA No. 970016 - Submissions to FDA
and Responses Through FDA Approval.**

05/21/97 Fax inquiry and comments from FDA
concerning outstanding issues on
preliminary review of PrePMA submission
of 03/31/97.

06/16/97 Formal premarketing approval (PMA)
application submitted by Gynecare, Inc.
for ThermaChoice™ Uterine Balloon
Therapy Device and response to FDA
facsimile of 05/21/97.



08/11/97 PMA amendment submitted in response to FDA telephone calls of 08/08/97 concerning manufacturing instructions, quality assurance procedures and testing matters.

08/29/97 PMA amendment submitting interim update Table of Contents.

10/06/97 Panel Hearing.

10/10/97 Post panel letter from FDA and notice of deficiency discussed in teleconference of 10/1/97.

10/16/97 Followup response to FDA teleconference of 10/16/97 concerning engineering tests and clinical aspects.

10/17/97 Response to deficiency set forth in 10/10/97 letter submitted.

10/20/97 Followup response to FDA teleconference of 10/08/97 concerning software validation issues in letter of 10/10/97.

10/21/97 Followup response to FDA teleconference of 10/21/97 concerning engineering test data sent 10/16/97.

10/31/97 PMA amendments submitted to comply with FDA panel conditions in status letter of 10/10/97.

11/25/97 Supplemental amendment notifying FDA of merger of Gynecare, Inc./Ethicon, Inc. on November 20, 1997.

12/10/97 Copy of final labeling changes submitted in response to FDA teleconference of 12/10/97.

12/12/97 PMA approved by FDA to Gynecare, Inc./Ethicon, Inc.

12/31/97 PMA amendments and submission of two copies of final labeling to comply with conditions of approval.